

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Inventors : Dieter MANSTEIN
Appln. Serial No. : 10/599,519
Filed : June 22, 2007
Entitled : METHOD FOR DERMATOLOGICAL TREATMENT
 USING CHROMOPHORES
Group Art Unit : 1617
Examiner : Audrea J. Buckley
Confirmation No. : 1188

BRIEF ON APPEAL

TABLE OF CONTENTS

I.	REAL PARTY IN INTEREST.....	2
II.	RELATED APPEALS AND INTERFERENCES.....	2
III.	STATUS OF CLAIMS.....	2
IV.	STATUS OF AMENDMENTS.....	3
V.	SUMMARY OF CLAIMED SUBJECT MATTER	3
VI.	GROUNDS OF REJECTION TO BE REVIEWED.....	4
VII.	ARGUMENTS	5
1.	Prior Art Relied on by the Examiner	5
2.	Relevant Case Law and Procedure(s).....	6
3.	Issues on Appeal.....	9
4.	Conclusion.....	21
	CLAIMS APPENDIX	A-1 to A-5
	EVIDENCE APPENDIX	B-1
	RELATED PROCEEDINGS APPENDIX.....	C-1

TABLE OF AUTHORITIES

CASES

<i>Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.</i> , 927 F.2d 1200, 1207 (Fed. Cir. 1991).....	8
<i>Application of Lundsford</i> , 357 F.2d. 385, 389-90 (CCPA 1966)	9
<i>Ashland Oil, Inc. v. Delta Resins & Refractories</i> , 776 F.2d. 281, 296 (Fed. Cir. 1985)	9
<i>Diversitech Corp. v. Century Steps, Inc.</i> , 850 F.2d 675, 679 (Fed. Cir. 1998)	7
<i>Graham v. John Deere</i> , 383 U.S. 1, 148 USPQ 459 (1966)	6, 7
<i>In re Beattie</i> , 974 F.2d 1309, 1311-12 (Fed. Cir. 1992).....	7
<i>In re Dow Chem. Co.</i> , 837 F.2d 469, 473 (Fed. Cir. 1988).....	8
<i>In re Napier</i> , 55 F.3d 610, 613 (Fed. Cir. 1995).....	8
<i>In re O'Farrell</i> , 853 F.2d. 894, 903-04 (Fed. Cir. 1988).....	8
<i>In re Paulsen</i> , 30 F.3d 1475, 1482 (Fed. Cir. 1994)	8
<i>In re Rouffet</i> , 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998)	6
<i>In re Translogic Technology, Inc.</i> , 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007)	8
<i>KSR International Co. v. Teleflex Inc.</i> , 127 S. Ct. 1727, 1741 (2007).....	7, 8
<i>Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.</i> , 75 F.3d 1568, 1573 (Fed. Cir. 1996).....	7

<i>W.L. Gore & Associates, Inc. v. Garlock, Inc.,</i> 721 F.2d 1540 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).....	9
---	---

STATUTE

35 U.S.C. § 103(a).....	Passim
-------------------------	--------

PATENT PROCEDURES

MPEP 2143.01(V), (VI))	14
------------------------------	----

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Inventors : Dieter MANSTEIN
Appln. Serial No. : 10/599,519
Filed : June 22, 2007
Entitled : METHOD FOR DERMATOLOGICAL
TREATMENT USING CHROMOPHORES
Group Art Unit : 1617
Examiner : Audrea J. Buckley
Confirmation No. : 1188

United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

On January 3, 2012, Appellant submitted a Notice of Appeal to the U.S. Patent and Trademark Office (the “Patent Office”) from the final rejection of claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32 contained in the Final Office Action dated September 2, 2011 for the above-identified patent application. On December 2, 2011, Appellant submitted a Response to Final Office Action (“Response to Final”), in which arguments were presented to overcome the rejection of claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32. After receipt of an Advisory Action dated December 19, 2011, Appellant submitted a Notice of Appeal on January 3, 2012, together with a Request for Pre-Appeal Conference.

A Pre-Appeal Conference Decision dated January 30, 2012 indicated that the application remains under appeal. Thus, in accordance with 37 C.F.R. § 41.37, this brief is being submitted in support of the appeal of the final rejection of pending claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32. For at least the reasons set forth below, the final rejection of pending claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32 should be reversed.

I. REAL PARTY IN INTEREST

The real party in interest is the General Hospital Corporation of Boston, Massachusetts. The General Hospital Corporation is the assignee of the entire right, title and interest in the present application.

II. RELATED APPEALS AND INTERFERENCES

Appellant and the Appellant's legal representatives are unaware of any appeals or interferences related to the present application that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32 are under consideration in the above-referenced application, all of which have been finally rejected.

In particular, claims 1, 3, 4, 6-9 and 27-30 stand finally rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Publication No. 2003/0159615 by Anderson et al. (the “Anderson Publication”) in view of U.S. Patent No. 6,565,532 issued to Yuzhakov et al. (the “Yuzhakov Patent”). Claims 5, 11, 13, 16, 17, 20-23, and 25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Anderson Publication in view of the Yuzhakov Patent and further in view of U.S. Patent No. 5,836,998 issued to Mueller et al. (the “Mueller Patent”). Claim 24 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the Anderson Publication in view of the Yuzhakov Patent and the Mueller Patent, and further in view of U.S. Publication No. 2002/0091311 of Eppstein et al. (the “Eppstein Publication”).

Appellants appeal from the final rejection of all pending claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32. A copy of all of the pending claims is attached hereto in the Claims Appendix.

IV. STATUS OF AMENDMENTS

No amendments were made to the pending claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32 in the Response to Final that was filed on December 2, 2011 in response to the final rejection of the claims contained in the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

An exemplary embodiment of the disclosure of the present application, as recited in independent claims 1 and 11, relates to a method for fractional

wounding of skin that includes applying a chromophore (e.g., in a specific pattern as recited in independent claim 1) to an area of skin, and then applying electromagnetic energy to the area to generate a plurality of thermally-damaged regions or regions of thermal injury in at least an epidermal portion of the skin based on an interaction between the electromagnetic radiation and the at least one chromophore. (See specification, page 4, line 27-page 5, line 6; and page 8, lines 19-28). “Thermal injury” or “damage” can be defined as cell death in one or more regions of the dermal tissue of interest, or stimulation of the release of cytokines, heat shock proteins, and other wound healing factors without stimulating necrotic cell death. (See, e.g., specification, page 5, line 34—page 6, line 3).

As further recited in independent claim 11, a mask having a specific pattern can be applied over the area of skin to generate regions of thermal injury in the desired pattern. (See, e.g., specification, page 8, line 33—page 9, line 7). A generation of such regions of thermal injury or damage can lead to desirable results such as an improvement in the appearance of aged or sun-damaged skin.

VI. GROUNDS OF REJECTION TO BE REVIEWED

The grounds of rejection on appeal to be reviewed are as follows:

- a.) Whether claims 1, 3, 4, 6-9 and 27-30, which stand finally rejected under 35 U.S.C. § 103(a), are unpatentable over the Anderson Publication in view of the Yuzhakov Patent;
- b.) whether claims 5, 11, 13, 16, 17, 20-23, and 25, which stand finally rejected under 35 U.S.C. §103(a), are unpatentable over the Anderson

Publication in view of the Yuzhakov Patent and further in view of the Mueller Patent; and

c.) whether claim 24, which stands finally rejected under 35 U.S.C. § 103(a), is unpatentable over the Anderson Publication in view of the Yuzhakov Patent and the Mueller Patent, and further in view of the Eppstein Publication.

VII. ARGUMENTS

1. Primary Prior Art relied on by the Examiner

The Examiner relies on an alleged combination of the Anderson Publication and the Yuzhakov Patent for maintaining the final rejection under 35 U.S.C. § 103(a) of claims 1, 3, 4, 6-9 and 27-30; an alleged combination of the Anderson Publication, the Yuzhakov Patent and the Mueller Patent for maintaining the final rejection under 35 U.S.C. § 103(a) of claims 5, 11, 13, 16, 17, 20-23, and 25; and an alleged combination of the Anderson Publication, the Yuzhakov Patent, the Mueller Patent and the Eppstein Publication for maintaining the final rejection under 35 U.S.C. § 103(a) of claim 24.

The Anderson Publication relates to microparticles that can be implanted in the dermis to form permanent tissue markings (e.g., tattoos), where such markings may optionally be removed at a later time by application of energy, such as optical radiation. (See Anderson Publication, Abstract, and paras. [0016], [0133], and [0134]).

The Yuzhakov Patent relates to microneedle arrays that can be used, *inter alia*, to apply markings to the epidermis of the skin that do not enter the dermal layer. (See Yuzhakov Patent, Abstract; col. 3, lines 54-59; col. 8, lines 1-14; and col. 41, lines 36-45).

The Eppstein Publication describes methods and apparatus for increasing permeability of a biological membrane using a pyrotechnic charge to form openings therein. (See Eppstein Publication, Abstract, and paragraph [0041]). The methods and apparatus of Eppstein can be used with a substrate containing pigments, where the pigments are forced into the skin by the charge to form a tattoo. (*Id.*, para. [0044]).

The Mueller Patent describes the use of a stencil for body art whereby a stain is applied to a predetermined epidermal area delineated by the stencil. (See Mueller Patent, col. 1, line 65-col. 2, line 11).

2. Relevant Case Law and Procedure(s)

35 U.S.C. § 103 Case Law

"To reject claims in an application under Section 103, an examiner must show an unrebutted *prima facie* case of obviousness." *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998). The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

Under Section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Indeed, to sustain a rejection under 35 U.S.C. § 103(a), there must be some teaching, other than the instant application, to alter the prior art to arrive at the claimed invention. “The problem confronted by the inventor must be considered in determining whether it would have been obvious to combine the references in order to solve the problem.” *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 679 (Fed. Cir. 1998).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the Appellant (the “TSM test”). See *In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit’s application of the TSM test, see *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741,

(2007), the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; see also *In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, “the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure.” *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O’Farrell*, 853 F.2d. 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in Appellant’s disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. See *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

To establish obviousness, the prior art references must be evaluated as a whole for what they fairly teach and neither the references' general nor specific teachings may be ignored. *Application of Lundsford*, 357 F.2d. 385, 389-90 (CCPA 1966). A reference must be considered for all that it teaches, not just what purportedly points toward the invention but also that which teaches away from the invention. *Ashland Oil, Inc. v. Delta Resins & Refractories*, 776 F.2d. 281, 296 (Fed. Cir. 1985); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

3. Issues on Appeal

Appellant respectfully asserts that the Anderson Publication, taken in a purported combination with the Yuzhakov Patent does not disclose, teach or suggest the subject matter recited in claims 1, 3, 4, 6-9 and 27-30 of the present application; that a purported combination of the Anderson Publication, the Yuzhakov Patent and the Mueller Patent does not disclose, teach or suggest the subject matter recited in claims 5, 11, 13, 16, 17, 20-23, and 25; and that a purported combination of the Anderson Publication, the Yuzhakov Patent, the Mueller Patent and the Eppstein Publication does not disclose, teach or suggest the subject matter recited in claim 24. Appellant further asserts that the Anderson Publication teaches away from Appellant's claimed invention, and that the Anderson Publication is not combinable with the Yuzhakov Patent, as relied on at least in part by the Examiner to support a rejection of all pending claims 1, 3-9, 11, 13, 16, 17, 20-25 and 27-32.

a. **Claims 1, 3, 4, 6-9 and 27-30**

Independent claim 1 relates to **a method for fractional wounding of skin** and recites, *inter alia*, applying at least one chromophore in a specific pattern to a predetermined area of skin, where the specific pattern **corresponds to a desired pattern of fractional wounding**, and applying electromagnetic radiation to the predetermined area of skin to generate a plurality of thermally-damaged regions in at least an epidermal portion of the skin based on an interaction between the at least one chromophore and the electromagnetic radiation.

The Examiner acknowledges that the Anderson Publication only describes deposition of microparticles into the dermis. (See Final Office Action, page 4). For example, the Anderson Publication states, in part:

“Tissue markings in skin must be properly placed to provide permanent markings. Skin is composed of the outermost epidermis, generated by the constantly dividing stratum basale, and the underlying dermis. Dermal cells, such as fibroblasts, mast cells, and others, which do not generally replicate, are located within a resilient proteinaceous matrix. It is the upper dermis, below the stratum basale, into which the microparticles are implanted to provide a tissue marking (such as a tattoo).”

(Anderson Publication, para. [0133]; emphasis added).

Thus, the Anderson Publication explicitly states that such markings must be placed below the stratum basale to be permanent, and thereby be removable only by exposure to energy.

The Examiner contends that the epidermal layer would be “fractionally wounded” by the application of the chromophores. (See Final Office Action, page 4). Appellant respectfully points out that such alleged fractional wounding of the

epidermal layer, if it were caused by application of chromophores to the dermis, would be mechanical in nature and clearly different from the thermally-damaged regions generated based on an interaction between the at least one chromophore and the electromagnetic radiation, as recited in independent claim 1.

In the Advisory Action, the Examiner states that the “removable tattoo” method described in the Anderson Publication describes radiation-induced breakage of deposited pigment particles, and alleges that such process can result in damage to neighboring skin structures. The Examiner further states that it is the position of the Office that “this process induces thermal changes in the skin because it is extremely unlikely that the energy absorbed by the pigment particles is perfectly converted into breakage of the particles without any release of heat.” (See Advisory Action, page 2).

Appellant respectfully disagrees with this position, and asserts that the Anderson Publication teaches away from creating thermal damage in the skin tissue when exposing the microparticles to energy such as optical energy. For example, the Anderson Publication describes the use of fluences that are “well tolerated by the skin” and that “higher laser fluencies that do not injure the tissue can be used...” (See Anderson Publication, para. [0150]; **emphasis added**). The Anderson Publication further notes that “Ideally, short, powerful light pulses are absorbed specifically by tattoo pigment particles with little or no absorption by surrounding tissue, thereby causing the particles of pigment to break apart with minimal damage to neighboring skin structures.” (*Id.*; **emphasis added**).

Indeed, the Anderson Publication is directed towards providing permanent skin markings by implanting pigment particles into the dermis, where such markings can be later removed by applying light pulses to the particles. The Anderson Publication describes only using light pulses having properties that are selected to avoid or minimize any damage to the skin tissue when such pulses interact with the particles. Accordingly, Appellant asserts that the Anderson Publication teaches away from generating thermal damage in the skin tissue. The Anderson Publication clearly fails to teach or suggest certain recited features of independent claim 1 such as the formation of any desired pattern of fractional wounding of the skin or producing a plurality of thermally-damaged regions, as such thermal damage or thermal injury is defined in the present application. (See, e.g., specification, page 5, line 34—page 6, line 3).

The Examiner then relies on a purported combination of the Anderson Publication with the Yuzhakov Patent in rejecting independent claim 1 and claims 3, 4, 6-9 and 27-30 that depend therefrom. (See Final Office Action, page 3). As an initial matter, the Yuzhakov Patent describes the use of microneedle arrays, *inter alia*, to introduce substances, such as ink or pigment, into the epidermal layer to produce semi-permanent markings. (See Yuzhakov Patent, Abstract; and col. 3, lines 54-59). The Yuzhakov Patent does not mention any application of electromagnetic radiation to such pigment or ink, or any other process that would lead to thermal damage or thermal injury of the skin tissue. Accordingly, the Yuzhakov Patent fails to cure the deficiencies in the Anderson Publication described above, as it fails to disclose or suggest the concept of thermal damage of skin

tissue. Thus, the purported combination of the Anderson Publication with the Yuzhakov Patent relied on by the Examiner also fails to disclose, teach or suggest the subject matter recited in independent claim 1, and in claims 3, 4, 6-9 and 27-30 that depend therefrom for at least the same reasons.

Further, Appellant respectfully asserts that the Anderson Publication is *not combinable* with the Yuzhakov Patent in the manner contemplated by the Examiner. The Anderson Publication explicitly describes the placement of microparticles in the dermis, below the stratum basale, to form permanent skin markings that are removable only by exposure to optical energy. (See Anderson Publication, Title; and paras. [0001], [0133], [0134], and [0143]). In contrast, the Yuzhakov Patent describes the use of microneedle arrays, *inter alia*, to introduce substances, such as ink or pigment, into the **epidermal** layer (i.e., above the stratum basale) to produce semi-permanent markings that would disappear from the skin after a time period. (See Yuzhakov Patent, Abstract; col. 3, lines 54-59; col. 8, lines 1-14; col. 41, lines 36-45; and col. 42, lines 3-10). The Yuzhakov Patent describes the well-known biological effect that markings placed in the epidermal layer, **above** the stratum basale, will not be permanent and will gradually disappear as the epidermal cells are continuously sloughed off. (See, e.g., Yuzhakov Patent, col. 42, lines 3-10). One of ordinary skill in the art would not introduce the particles of Anderson into the epidermis (which the Anderson Publication teaches away from as noted above), and then expose the particles to light energy to remove them (as described in the Anderson Publication), because such epidermal markings would disappear spontaneously, and the methods

described in the Anderson Publication would be **unnecessary** for removal of such temporary markings.

Accordingly, a purported combination of the Anderson Publication and the Yuzhakov Patent, as suggested by the Examiner, would render the invention described in the Anderson Publication unsatisfactory for its intended purpose and/or change the principle of the method described in the Anderson Publication (viz., the formation of permanent markings that can only be removed by exposing pigmented dermal particles to light pulses), and therefore such combination cannot be used to render the present claims obvious. (See Manual of Patent Examining Procedure (MPEP), 2143.01(V), (VI)).

More generally, one of ordinary skill in the art would not look to either the Anderson Publication or the Yuzhakov Patent to purposely generate regions of thermal damage in a desired pattern of fractional wounding, much less combine them to do so. Neither of these publications that were relied on by the Examiner teaches, suggests, or discloses fractional wounding of skin in a desired pattern by exposing epidermal chromophores to electromagnetic radiation. Indeed, the Anderson Publication explicitly teaches away from generating such thermal damage, and also teaches away from providing chromophores in the epidermis, whereas the Yuzhakov Patent is silent with respect to using any form of electromagnetic radiation or generating any thermal damage in skin tissue. Accordingly, Appellant respectfully asserts that the alleged combination of the Anderson Publication and the Yuzhakov Patent relied on by the Examiner, even if

combinable (and Appellant does not concede that they are) fails to establish a *prima facie* case of obviousness.

As a side note, the Examiner states that the Anderson Publication and the Yuzhakov Patent are both directed to “tattoos created by damaging and implanting active agents into layers of the skin.” (See Final Office Action, page 5). Appellant notes that to the extent such tattoos are described in either reference, they are not provided in a **desired pattern of fractional wounding** that is used to produce a plurality of **thermally damage regions in at least an epidermal portion of the skin**, as recited in independent claim 1, as neither of these references teaches, discloses, or suggests any method of forming a desired pattern of fractional wounding. The “damaging” cited by the Examiner is merely incidental mechanical damage to the epidermal skin layer caused by penetration of the microneedles. Accordingly, Appellant asserts that one of ordinary skill would not look to the Anderson Publication to produce a plurality of **thermally damage regions in a desired pattern of fractional wounding**, as recited in independent claim 1, and the Yuzhakov Patent does not cure this deficiency.

Accordingly, for at least such reasons, the rejections of independent claim 1, and the claims which depend therefrom under 35 U.S.C. § 103(a) should be withdrawn.

In addition, with respect to claim 3, this claim depends from independent claim 1, and recites, *inter alia*, removing a first portion of the chromophore from the skin surface **prior** to applying the electromagnetic radiation. In the Final Office Action, the Examiner contends that the Anderson Publication

teaches such incomplete removal of chromophores “can be achieved by administering radiation to affect only a fraction of microparticles such as to reduce the color-intensity of a marking where the extent of photobleaching can be controlled by adjusting fluence per pulse and number of pulses administered,” citing paras. [0158] and [0173] of the Anderson Publication. (See Final Office Action, page 5). However, such partial removal or photobleaching of tissue markings as described in the Anderson Publication is achieved by irradiation of the markings, which is different from the partial removal of chromophores prior to applying the electromagnetic radiation, as recited in claim 3. Further, claim 3 recites a partial removal of chromophores from the surface of the skin. In contrast, the markings that may be partially removed by irradiation as described in the Anderson Patent are located in the dermis, which is well below the surface of the skin.

Turning to claim 4, this claim also depends from independent claim 1, and recites that, *inter alia*, the chromophore can be applied to the skin as a powder. The Examiner notes that the Anderson Publication teaches preparation of microparticulate chromophores by grinding dry powdered Rose Bengal and sifting it, citing Example 3 at para. [0169] of the Anderson Publication. (See Final Office Action, page 5). The Examiner then acknowledges that it is “not apparent” that the powder is implemented as a dry powder, and bases the rejection of claim 4 on an unsupported “obviousness rationale.” (*Id.*) The Examiner further alleges that the Anderson Publication teaches the powder and the “option” of implementing it as a suspension, and that it would therefore be obvious to one of ordinary skill that the

suspension was not a “necessary form” for the powder implementation. (*Id.*)

Appellant respectfully disagrees with the Examiner’s reasoning.

The only embodiments described in the Anderson Publication for applying the particles to skin tissue to form permanent markings include providing the powder in a suspension as an injectable tattoo ink, and not that the suspension is an “option” or “not a necessary form.” (See Anderson Publication, paras. [0130]-[0132], [0163], [0167], and [0172]). The permanent skin markings or tattoos described in the Anderson Publication are formed by introducing microparticles into the dermis as noted above, which is done by using needles to inject an ink or suspension of chromophores into the skin. (*Id.*) Contrary to the Examiner’s contention, Appellant respectfully asserts that the Anderson Publication fails to teach or suggest any application of chromophores to the skin surface in the form of a powder.

Concerning claim 6, this claim also depends from independent claim 1, and recites that, *inter alia*, the chromophore is applied to the skin in a specific pattern using an attachment medium. Claims 7-9 (which depend from claim 1) recite that the attachment medium is an adhesive, is light-activated, or is an acrylide, a derma-bond or a glue, respectively. The Examiner contends that various substances can be used to encapsulate the chromophore particles, acknowledging that the Anderson Publication does not teach the use of a particular glue (Epo-Tek 301) as an attachment medium, but alleging that one of ordinary skill in the art would be motivated to do so because it is “biocompatible and approved by the FDA for use in medical devices.” (See *id.*, page 7). The Appellant respectfully disagrees

with the Examiner's apparent contention that a coating material for chromophore particles, as described in the Anderson Publication, constitutes an "attachment medium" as recited in claims 6-9.

The Anderson Publication describes that the coated chromophores, or microparticles, can be used in a suspension, e.g., as a tattoo ink that can be injected into the dermis. (See Anderson Publication, paras. [0130]-[0132], [0163], [0167], and [0172]). Contrary to the Examiner's contention, Appellant respectfully asserts that the Anderson Publication fails to disclose, teach or suggest that any coating materials for chromophores can be used as an **attachment medium** to apply the chromophore to the skin in a specific pattern, as recited in claims 6-9.

Accordingly, Appellant respectfully asserts that purported combination of the Anderson Publication and the Yuzhakov Patent relied on by the Examiner, fails to disclose the recitations of claims 1, 3, 4, 6-9 and 27-30, as required to support the final rejection of these claims under 35 U.S.C. §103, for at least the reasons provided above, and further that these references are not even combinable to support any such rejection.

b. Claims 5, 11, 13, 16, 17, 20-23, and 25

As an initial matter regarding the 35 U.S.C. § 103(a) final rejections of claims 5, 11, 13, 16, 17, 20-23, and 25, Appellant respectfully asserts that the Anderson Publication is not combinable with the Yuzhakov Patent, as relied on (at least in part) by the Examiner to support the rejection of these claims, for at least

the reasons provided above with respect to claims 1, 3, 4, 6-9 and 27-30. Appellant further reasserts that the Anderson Publication teaches away from the claimed subject matter of the present invention, viz., a method for fractional wounding of skin, for at least the reasons described in detail above. Accordingly, Appellant respectfully asserts that claims 5, 11, 13, 16, 17, 20-23, and 25 are also patentable over the publications relied on by the Examiner for at least these reasons, and further in view of the additional reasons set forth herein below.

The Examiner further relies on a purported combination of the Anderson Publication, the Yuzhakov Patent, and the Mueller Patent for maintaining the final rejection of claims 5, 11, 13, 16, 17, 20-23, and 25. Independent claim 11 recites, *inter alia*, applying to a region of skin a chromophore and a mask having a specific pattern corresponding to a desired pattern of fractional wounding, and applying electromagnetic radiation to generate **regions of thermal injury in an epidermal portion of the skin** based on an interaction between the electromagnetic radiation and the chromophore. Claims 13, 16, 17, 20-23, and 25 depend from claim 11. Claim 5, which depends from independent claim 1, includes the recitation of the specific pattern of the chromophore being applied using at least one of a grid, a mesh, a roller, a stamp or a stencil. A purported combination of the Anderson Publication with the Yuzhakov Patent fails to render obvious the subject matter recited in these claims, for at least the reasons described above with respect to independent claim 1. The Mueller Patent relied on by the Examiner, which describes the use of a stencil to form a pattern of stain on the skin, fails to cure at least such deficiency. Accordingly, Appellant respectfully traverses the rejection of

claims 5, 11, 13, 16, 17, 20-23, and 25 based on a purported combination of the Anderson Publication, Yuzhakov Patent, and Mueller Patent.

c. Claim 24

The Examiner relies on a purported combination of the Anderson Publication, the Yuzhakov Patent, the Mueller Patent, and the Eppstein Patent for maintaining the final rejection of claim 24. Claim 24, which depends indirectly from independent claim 1, includes the recitation of the chromophore being a phase transition chromophore that includes paraffin. Appellant respectfully asserts that claim 24 is not obvious in view of the purported combination of the Anderson Publication and the Yuzhakov Patent for at least the same reasons provided above with respect to claim 1, and that the Mueller Patent, which describes the use of stencils, and the Eppstein Patent, which describes the formation of small openings in biological membranes using pyrotechnic elements, fail to cure this deficiency.

Further, the Eppstein Patent describes the use of paraffin as one material that can be used in a substrate, where such material can react chemically or outgas in response to the pyrotechnic elements. (See Eppstein Patent, para. [0044]). The substrate can further include pigments, which are distinct from the paraffin, such that a tattoo can be produced upon detonation of the pyrotechnic charges. (*Id.*) Although the Eppstein Patent describes an optional use of paraffin as a substrate material, Appellant respectfully asserts that the Eppstein Patent fails to teach or suggest the use of paraffin as a chromophore (e.g., a phase-change

chromophore) as recited in claim 24, and that it is the pigments that may be forced across a membrane to form a tattoo. Accordingly, Appellant respectfully traverses the rejection of claim 24 at least based on a purported combination of the Anderson Publication, Yuzhakov Patent, Mueller Patent, and Eppstein Patent.

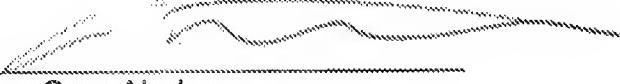
4. Conclusion

For at least the reasons indicated above, Appellant submits that the invention recited in the presently rejected claims of the present application, as discussed above, is new, non-obvious and useful. Reversal of the Examiner's final rejection of the claims is therefore respectfully requested.

Respectfully submitted,

Dated: March 5, 2012

By:


Gary Abelev
Patent Office Reg. No. 40,479

DORSEY & WHITNEY, L.L.P.
51 West 52nd Street
New York, New York 10019

Attorney(s) for Appellant
(212) 415-9200

CLAIMS APPENDIX

Claims as currently pending:

1. A method for fractional wounding of skin, comprising:

applying at least one chromophore in a specific pattern to a predetermined area of the skin, wherein the specific pattern corresponds to a desired pattern of fractional wounding of the skin; and

applying electromagnetic radiation to the predetermined area of the skin so as to produce a plurality of thermally-damaged regions in at least an epidermal portion of the skin based on an interaction between the at least one chromophore and the electromagnetic radiation.

2. (Canceled)

3. The method of claim 1, further comprising removing a first portion of the at least one chromophore from a surface of the skin prior to applying the electromagnetic radiation, wherein a second portion of the at least one chromophore remains in pores of the skin.

4. The method of claim 3 wherein the at least one chromophore is applied to the skin as a powder.

5. The method of claim 1 wherein the specific pattern is applied using at least one of a grid, a mesh, a roller, a stamp or a stencil.

6. The method of claim 1 wherein the specific pattern is applied using an attachment medium.
7. The method of claim 6 wherein the attachment medium is an adhesive.
8. The method of claim 6 wherein the attachment medium is light-activated.
9. The method of claim 7 wherein the attachment medium is at least one of an acrylide, a derma-bond or a glue.
10. (Canceled)
11. A method for fractional wounding of skin, comprising:
 - applying at least one chromophore to a predetermined area of the skin;
 - and
 - applying a mask with a specific pattern over the predetermined area of the skin, wherein the specific pattern corresponds to a desired pattern of fractional wounding of the skin; and
 - applying electromagnetic radiation to the predetermined area so as to generate regions of a thermal injury in at least an epidermal portion of the skin based on an interaction between the electromagnetic radiation and the at least one chromophore, wherein the regions are formed in a predetermined pattern.

12. (Canceled)

13. (Previously presented) The method of claim 11 wherein the mask is at least one of a grid, a mesh, a roller, a stamp or a stencil.

14-15. (Canceled)

16. The method of claim 11 wherein the mask protects the skin from fractional wounding and wherein the fractional wounding occurs where the skin is not in contact with the mask.

17. The method of claim 16 wherein the mask is at least one of a grid, a mesh or a stencil.

18-19. (Canceled)

20. The method of claim 16 wherein the mask comprises at least one chromophore reflector.

21. The method of claim 20 wherein the at least one chromophore reflector is at least one of a glass bead, a gold flake, a metal particle, a mirrored glass bead, a salt crystal, or a silica.

22. The method of claim 1 wherein the at least one chromophore comprises carbon.
23. The method of claim 1 wherein the at least one chromophore is a phase transition chromophore.
24. The method of claim 23 wherein the phase transition chromophore comprises paraffin.
25. The method of claim 1 wherein the specific pattern comprises at least one line.
26. (Canceled)
27. The method of claim 1, wherein the electromagnetic radiation has properties to generate a thermal injury to at least one region of the tissue proximal to the at least one chromophore, while avoiding a generation of the thermal injury in at least a portion of the predetermined area.
28. The method of claim 1, wherein a smallest dimension of the plurality of thermally damaged regions of the tissue is between about 1 μm and about 1000 μm .
29. The method of claim 1, wherein a smallest dimension of the plurality of thermally damaged regions of the tissue is between about 100 μm and about 800 μm .

30. The method of claim 1, wherein a distance between adjacent ones of the thermally damaged regions of the tissue is between about 10 μm and about 2000 μm .
31. The method of claim 1, wherein the thermally-damaged regions are further produced in a dermal portion of the skin.
32. The method of claim 11, wherein the regions of the thermal injury are further generated in a dermal portion of the skin.

EVIDENCE APPENDIX

Nothing to include.

RELATED PROCEEDINGS APPENDIX

Nothing to include.

4849-5591-2974\1